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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/267,511	03/12/1999	DOUGLAS E. BRENNEMAN	015280-37700	7130

20350 7590 06/03/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/03/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/267,511

Applicant(s)

BRENNEMAN ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

1. The request filed on March 22, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/267,511 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

2. Claims 2, 3, 14, 19-44 have been cancelled and claims 1, 4-11 and 13 have been amended as requested in the amendment of Paper No.18, filed on January 07, 2002. Claims 1, 4-13 and 15-18 are pending in the instant application.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on January 07, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. Claims 1, 4-13 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting fetal demise, decreased fetal birth weight and decreased fetal brain weight in a subject exposed to alcohol in utero by administration of ADNF polypeptides prior to alcohol exposure, does not reasonably provide

Art Unit: 1646

enablement for a method for reducing a condition associated with fetal alcohol syndrome by administration of ADFN polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record in Paper No.15 and the reasons that follow.

Claims 1, 4-13 and 15-18 of the instant application are directed to a method for reducing a condition associated with fetal alcohol syndrome in a subject who is exposed to alcohol *in utero* by administration of ADFN polypeptides. The instant specification provides information only about four parameters (conditions) associated with fetal alcohol syndrome that were evaluated by practicing the claimed method, in particular, fetal survival, fetal birth weight, fetal brain weight and levels of VIP mRNA. However, other conditions that are associated with fetal alcohol syndrome include, for example, changes in memory and learning, coordination, skeletal, facial, organ and brain deformities etc. The instant specification fails to provide any data to support the claimed method for reducing conditions other than fetal survival, fetal weight and fetal brain weight. In the absence of such information in the instant specification and in prior art a skilled artisan would have to resort to a substantial amount of undue experimentation involving the investigation of effects of administration of mixture of ADFN I and III polypeptides on other conditions associated with fetal alcohol syndrome.

Declaration of Dr. Brennehan was fully considered and has been found to be satisfying to overcome rejection based on use of rodent models for fetal alcohol syndrome. However, the Declaration was not persuasive in regard to timing of treatment with ADFN polypeptides. In particular, according to the data discussed in the Declaration, administration of ADFN

Art Unit: 1646

polypeptides 30 minutes before exposure to alcohol and 1 or 3 hours after exposure to ethyl alcohol leads to the reduction of conditions associated with fetal alcohol syndrome, such as fetal demise, fetal birth weight, fetal brain weight. However, these limitations (administration of ADNF 1 or 3 hours after exposure to alcohol) are not described in the instant specification. Moreover, the claims in their broadest interpretation are directed to a method for reducing a condition associated with fetal alcohol syndrome by administration an ADNF polypeptide without any limitation of timing of the administration. Therefore, the claims encompass administration of ADNF polypeptides before exposure to alcohol as well as 1 hour, 3 hours, 24 hours, days, months and more after the exposure to alcohol. The instant specification fails to provide any evidence or sound scientific reasoning that would support the conclusion that administration of ADNF polypeptides to a one-week-old subject who was exposed to alcohol in utero would lead to reduction of a symptom associated with fetal alcohol syndrome, such as reduced brain weight, for example. One of ordinary skill on the art would not reasonably expect that a condition such as reduced brain weight could be reversible by administration of ADNF polypeptides.

Applicant further submits that “[t]he specification clearly teaches one of skill in the art the appropriate dosage of the ADNF peptide to use” (page 12, fourth paragraph of the Response). However, the instant specification only discloses range of the dose to be used in the pretreatment before the exposure to alcohol. The instant specification fails to disclose an amount of ADNF peptides sufficient to reduce a condition associated with fetal alcohol syndrome to be given at time other than 30 minutes pretreatment. The Brenneman Declaration, again, supports the experimental dose given after 1 and 3 hours after exposure to alcohol, however, this information

Art Unit: 1646

is not provided in the instant specification, thus leaving a skilled artisan have to resort to substantial amount of undue experimentation involving the variation in the amount of administration of ADNF polypeptides.

In view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is found to be enabling only for a method for reducing a condition associated with fetal alcohol syndrome, such as fetal demise, fetal birth weight, fetal brain weight and levels of VIP mRNA by administration of ADNF polypeptides 30 minutes prior to alcohol exposure. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use the full scope of Applicants' invention as currently claimed.

7. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and ambiguous because it is not clear how to interpret "a method for reducing [death of the subject *in utero*]". Death is not a condition of degree, so it is unclear how to reduce "death".

Conclusion

8. No claim is allowed.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/267,511

Page 7

Art Unit: 1646

Olga N. Chernyshev, Ph.D.

May 31, 2002

OC

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud